DEPARTMENT OF HEALTH AND HUMAN SERVICE

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Southwest Region

Food and Drug Administration
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April 29, 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Steve Burd
President
Safeway, Inc.
5918 Stoneridge Mall Road
Pleasanton, California 94588-3229

Ref #: DEN-04-07

Dear Mr. Burd:

On February 3-9, 2004, we inspected your facility located at 4600 Stapleton Drive South, Denver, Colorado, 80127. We found that you have serious deviations from the seafood Hazard Analysis Critical Control Point (HACCP) Regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. §342(a)(4). Accordingly, your refrigerated fresh and ready-to-eat fish and fishery products have been prepared, packed, or held under unsanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You may find this Act and the Seafood HACCP Regulation through links in FDA's home page at http://www.fda.gov .

During our inspection, the investigator provided the management at your facility with a form FDA 483, which presents his evaluation of your firm's performance regarding various aspects of the HACCP regulation. We received a letter dated March 24, 2004 from Mr. Rick Rodriguez, Distribution Center Manager, in response to the FDA 483. We did not find this response to adequately address the concerns we found during the inspection. A copy of Mr. Rodriguez' response is attached to this letter.

The deviations are as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur, and have a HACCP plan that, at a minimum, lists the critical control points, to comply with 21 CFR 123.6(a) and (c)(2). A critical control point (CCP) is defined in 21 CFR 123.3(b) as a "point, step, or procedure in a food process at which control can be applied, and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels." However, your firm's HACCP plan does not list the critical control point of refrigerated storage for controlling the food safety hazard of pathogen growth and toxin formation. Thus, although you have a CCP for "Refrigerated Product Receiving," you do not have a CCP for storage to ensure that the products in storage do not become adulterated. We note that in your response letter dated March 24, 2004, you assert, "Additional CCP for Product Storage is not justified." However, you do not provide any support for this claim. While we understand that you have installed a continuous temperature monitoring system in your refrigerated cooler, you have provided no information demonstrating that you intend to monitor that the equipment is, in fact, functioning on a continuous basis. Maintaining adequate refrigerated temperatures (i.e., at or below 40° F) will prevent the growth and potential toxin formation of pathogenic microorganisms of public health significance. As a refrigerated food storage warehouse, we expect refrigerated storage to be a critical control point necessary to ensure the safety of your products.

2. You must have a HACCP plan that, at a minimum, lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan lists a monitoring procedure at the receiving critical control point that is not adequate to control the growth and potential toxin formation of pathogenic microorganisms. The procedure stated in your procedure does not ensure that a representative number of containers are checked at receipt. Your response does not adequately address correction of this deviation. You state in your letter of March 24, 2004, that [redacted] representative temperature will be checked" and the frequency will be [redacted] Your letter further cites page 158 of the Fish and Fisheries Products Hazards and Controls Guidance, 3rd (the Hazard Guide) as your reference. However, page 156 of the Hazard Guide recommends monitoring "a representative number of containers in the lot at the time of delivery". This will provide you with a better representation of the temperature(s) of your entire lot.

3. You must implement the record keeping system that you listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the receiving critical control point to control pathogen growth as listed in your HACCP plan. For example, records collected by our investigator during your inspection reveal that between [redacted], there were numerous occasions when the receiving temperature columns in the "Daily Receiving Inspection (HACCP) Record" were not completed.

4. You must also implement the monitoring procedures that you have listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedures listed at the receiving critical control point to control pathogen growth and potential toxin formation. Specifically, your plan lists that "internal product temperature" will be taken. However, our investigator observed your employee taking surface temperatures with an infrared thermometer. In addition, several of the daily receiving records collected by our investigator indicate that surface temperatures were entered rather than internal product temperatures, as evidenced by an 'X' adjacent to the column on the record for temperature. Furthermore, we note in your response letter that you state: "Appropriately train(ed) warehouse personnel manually check product surface temperature with a calibrated dial/stem thermometer, or infrared Non Contact thermometer or electronic digital thermometer." If you plan to use various types of thermometers and procedures other than taking internal temperature you should amend your HACCP plan to reflect your actual practice(s).

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation such as a revised HACCP plan, copies of monitoring records, etc. or any other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP Regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations

Please send your reply to the letterhead address, Attention: Shelly L. Maifarth, Compliance Officer.

Sincerely,

B. Belinda Collins
District Director